

### **REMARKS**

Claims 1-22 are pending in the Application. No claim has been amended. Claims 21 and 22 are supported at least by original claims 19 and 20. A current listing of claims is provided herewith.

The pending claims stand variously rejected as discussed below. In view of the arguments presented herein, Applicants respectfully request reconsideration on the merits of the application.

#### **Obviousness-Type Double Patenting Rejection**

Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting over the pending claims of U.S. Application No. 09/828,016, U.S. Application No. 09/828,018, U.S. Application No. 09/827,863, U.S. Application No. 09/827,436 and U.S. Application No. 09/828,015. To obviate this rejection, Applicants submit herewith a terminal disclaimer.

#### **Rejections under 35 U.S.C. § 112, Second Paragraph**

Claims 4 and 13 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The Office Action states that it is unclear what is intended by use in the claims of "at least 75% active."

As set forth in the MPEP, the standard for determining compliance with the requirements of §112, second paragraph, is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. MPEP 2173.02. The MPEP also notes that definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

MPEP 2173.02.

With respect to the presently rejected claims, Applicants assert that the term "at least 75% active" is clear in light of the specification, as interpreted by one of skill in the art.

Applicants respectfully direct the Examiner's attention to page 6, lines 10-14 of the specification, where the term "active level" is defined as "the level of desired material in the

ingredient....” An example is provided: “for fiber containing ingredients, the active level would be the actual percent fiber in the ingredient, as measured by the method for quantifying fiber as detailed in the present application.” In addition, a detailed protocol for determining both amino acid and fiber levels in a given food, i.e., protocols for determining their activity, are provided in the specification at pages 28-30 and 31-38, respectively.

Accordingly, Applicants assert that the claims fully comply with §112, second paragraph. Withdrawal of the rejection is respectfully requested.

#### **Rejections under 35 U.S.C. § 103(a)**

Claims 1-3, 5-12 and 14-18 are rejected under 35 U.S.C. § 103(a) as being obvious over Howard (U.S. Patent No. 4,900,566) in view of Michnowski (U.S. Patent No. 4,859,475).

Claims 4 and 13 are rejected as being obvious over Howard and Michnowski in further view of Wong (U.S. Application Publication No. 20020037355).

These rejections are traversed as discussed below.

To establish *prima facie* obviousness: 1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the teachings; 2) there must be a reasonable expectation of success; and 3) the references must teach or suggest all of the claimed limitations. MPEP 2142. Applicants respectfully assert that the Office Action does not set forth a *prima facie* case of obviousness with respect to the presently pending claims.

#### **Howard in view of Michnowski**

Howard discloses a meal replacement bar comprising a protinaceous material and a carbohydrate material, to be used in conjunction with a very low calorie diet. Col. 1, lines 10-15. Michnowski, on the other hand, discloses a high protein, low or no lactose, vitamin and mineral-fortified, nutritionally balanced snack that is shelf-stable. Abstract, Col. 3, line 28. It is respectfully asserted that neither reference, nor the general knowledge available in the art, compels modification or combination of these references. In particular, Michnowski, which teaches that “the nutritional bars of the present invention can be produced with the substantial elimination or complete elimination of milk or milk products” and Howard, which teaches that

“especially preferred” proteins are milk proteins such as Lactein 60 “comprising at least 60% of milk proteins,” would certainly not be combined.

Moreover, there is no suggestion or motivation, either in Howard, Michnowski or the knowledge available to those of skill in the art, to modify or combine the references with respect to the fiber content of the respective bars. Michnowski incorporates some dietary fiber, Howard actually teaches away from using fiber in bars. More particularly, Michnowski specifies that suitable amounts are about 3% to about 8%...” Col. 6, lines 53-55. In contrast, Howard teaches away from using fiber altogether:

By using a [non-fibrous] carbohydrate material as defined above, the disadvantages associated with the use of fibrous materials are avoided. In particular, the carbohydrate material used in the invention can provide a composition which avoids the unacceptable viscosity characteristics of compositions based on gums such as guar gum, and the poor mouthfeel of compositions including bran or like fibre. Col. 5, lines 37-44 (emphasis added).

In view of the foregoing, Applicants respectfully submit that no suggestion exists to modify the cited references. To the contrary, one of skill in the art would be dissuaded from combining the references in view of Howard’s teaching away.

Even assuming *arguendo* that a fortuitous combination of Howard and Michnowski could be made, the above-quoted passage suggests that there would be no reasonable expectation of success in the combination. That is, Howard’s non-fiber, lactose-containing bar would not likely be considered successfully combinable with Michnowski’s non-lactose, fiber-containing bar.

In contrast to the cited references, the present Application is directed to foods that combine the benefits of taste, balanced nutrition and convenience. Claim 1 is directed to a nutritionally balanced food having a particular water activity level and comprising, on a 100 kcal reference serving basis, at least 5 grams of an amino acid source, less than 3 grams of a digestible fat and a carbohydrate that provides the balance of the total caloric value and has at least about 2.5 grams of dietary fiber.

Even assuming *arguendo* that a suggestion exists to also combine the references, and that an expectation of success exists in doing so, the cited references still do not teach or suggest all of these limitations, either alone or in combination. In particular, Howard and Michnowski, taken separately or combined, do not teach or suggest, among other things, the claimed amount of dietary fiber.

Contrary to the assertions in the Office Action, the bar of Howard does not contain fiber. In fact, Howard specifically excludes fiber from the definition of carbohydrate:

However, it is to be understood that the indigestible carbohydrate should not be fibre as such, that is to say the indigestible portion of the carbohydrate material should be non-fibrous. Col. 5, lines 7-11.

Despite this specific disclaimer of fiber, the rejection appears to be based, in part, on the discussion of the prior art in the Howard patent ("Amounts within the claimed amounts are disclosed in col. 2, lines 35-44"). Columns 1-3, including the portion cited in the Office Action, includes a summary of the teachings of EP 0,127,287, WO 80/02226 and GB 1,356,370. EP 0,127,287 concerns a bar designed for the treatment of diabetes that includes guar gum as a source of soluble fiber. Col. 2, lines 45-47. With respect to this prior art bar, Howard teaches:

However, because of that consideration (essential to the earlier invention) the earlier bars and the process of producing them suffer from disadvantages associated with the gum ingredient...guar gums because of their viscosity characteristics can lead to the production of unsatisfactory bars. Col. 2, lines 51-57.

The latter two publications concern not a ready-to-eat food, but dry powder compositions adapted for rapid dispersion in water to be used as meal replacements in weight loss programs and are thus not applicable to the pending claims. Accordingly, not only do the formulations of Howard not include fiber, but Howard actually teaches away from the use of fiber in meal replacement bars: "known bars have a poor taste," and "[prior art] bars have to date proved to be unsatisfactory." Col. 3, lines 30-36. Prior art references must be considered in their entirety, including portions that would lead away from the claimed invention. MPEP 2141.02.

Michnowski does not cure the deficiencies of Howard with respect to fiber or otherwise. Although Michnowski teaches that "dietary fiber can be included in the nutritive bar," Col. 6, line 51, the amounts of fiber taught by Michnowski are not sufficient to meet, and therefore do not teach or suggest, the amounts of fiber required by the present claims. Michnowski teaches that "suitable amounts are about 3% to about 8%, preferably about 5% by weight fiber, based upon the weight of the final product." Col. 6, lines 53-55. Michnowski further teaches that a serving size is about 300 calories. Col. 5, lines 46-49. Thus, upon calculating the amount of fiber per 100 kcal reference serving it is determined that:

3 to 8% of 71 g = 2.13 to 5.68 g fiber per 300 calorie bar

2.13 to 5.68 g fiber per 300 calorie bar = 0.71 to 1.89 g fiber per 100 kcal reference serving.

Therefore, Michnowski does not teach or suggest the claimed amount of fiber, i.e., at least about 2.5 grams of dietary fiber per 100 kcal reference serving.

Moreover, in accordance with the present specification, the references teach that the further addition of fiber is not simply a matter of routine optimization. For example, the present specification teaches:

Also, it is known that decreasing a snack food's fat level while increasing its dietary fiber and protein levels can, depending on the magnitude of changes, seriously compromise processability, taste and texture. Page 3, lines 3-4.

An additional processing challenge exists for baked goods, as the incorporation of high levels of protein and dietary fiber results in the loss of dough elasticity. Here, the snack fails to process well as there are generally not enough structure forming components left in the formulation to permit dough sheeting. Page 3, lines 28-30.

As mentioned above, Howard specifically excludes fiber, noting the poor mouthfeel of compositions including bran or like fiber. Therefore, Howard provides further evidence that increasing fiber in ready-to-eat foods is not simply a matter of adjusting levels of known ingredients.

Similarly, the bar described in Michnowski includes fiber, but not enough. The claimed requirement for 2.5 grams of fiber per serving is significant. This amount of fiber is an important feature of the claimed invention because, as taught by the present specification, 2.5 grams of fiber per reference serving is the FDA minimum requirement for claims that a product is a "good source of fiber." Page 17, lines 32-33. Were increasing fiber content to meet the FDA requirement simply a matter of routine optimization of ingredients, the prior art, including Michnowski, would advocate the addition of greater amounts of fiber. Applicants have successfully incorporated the fiber content to provide nutritionally balanced snacks.

Therefore, Applicants respectfully assert that a *prima facie* case of obviousness has not been established.

In addition, none of the caselaw cited in the Office Action stands for the proposition that food compositions are subject to different standards of patentability than other compositions. In fact, the legal principle enunciated in *In re Levin* supports patentability of the claimed invention:

Invention may reside in a composition of matter formed by the intermixture of two or more ingredients which results in a product possessing characteristics of utility that are new, additional and materially different from the property or properties which the several ingredients individually do not possess in common. *In re Levin*, 84 USPQ 232, 234. (Fed. Cir. 1949).

The instant specification establishes that in providing nutritious, tasty ready-to-eat foods having the specified levels of nutrients, Applicants have provided an invention that possesses characteristics that are new and useful.

Finally, Applicants note that *In re Levin* does not stand for the principle that recipes are *per se* unpatentable.<sup>1</sup> Examples of patented recipes can be found at least in U.S. Patent No. 6,475,549 to Ruhl (ceasar dressing) and U.S. Patent No. 6,207,205 to Patel (spicy popcorn).

For the above reasons, it is respectfully asserted that the presently pending claims are not obvious over Howard in view of Michnowski. Withdrawal of the rejection is therefore respectfully requested.

#### Howard in view of Michnowski in further view of Wong

In addition to the limitations of claim 1, claims 4 and 13 further require 75% active amino acid and fiber sources, soluble fiber having particular viscosity levels and particle size and water absorption.

Citing Wong, the Examiner necessarily concedes that Howard and Michnowski are deficient regarding the further fiber limitations of claims 4 and 13.

Applicants respectfully submit that the § 103(a) rejection requiring a combination of Howard, Michnowski and Wong is improper pursuant to 35 U.S.C. § 103(c) because the Wong application is only available as a reference under section 102(e), and not under section 103(a). Section 103(c) dictates the following:

Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

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<sup>1</sup> Applicants in no way concede that the presently claimed invention is merely a recipe.

Applicants submit that the subject matter of the Wong Application as well as the claimed invention in the present Application were, at the time the claimed invention was made, owned by Procter & Gamble or subject to an obligation of assignment to Procter & Gamble. Accordingly, using the Wong reference to reject the claims under 103(a) is improper. Because Wong is not available as a reference upon which the Examiner can base the §103 rejection, reconsideration and withdrawal of the rejection are respectfully requested.

**Allowable Subject Matter**

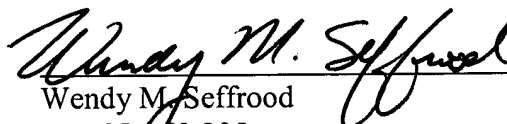
The Office Action indicates that claims 19 and 20 would be allowable if rewritten in independent form including all the limitations of the base claim and any intervening claims. Accordingly, new claims 21 and 22, which incorporate the subject matter of claims 19 and 20 and the base claim are in condition for allowance. Notification to that effect is earnestly solicited.

**CONCLUSION**

In view of the foregoing, reconsideration and allowance of claims 1-22 are respectfully requested. The Examiner is strongly encouraged to contact the undersigned by telephone at the Examiner's convenience should any issues remain with respect to the Application.

Respectfully submitted,

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